Product ingredient source information may be entitled to confidential treatment

NON – FEE

DATE OUT: 18/ June/ 2004

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.:298882 **File Reg. No.:** 42750-72
PRODUCT NAME: Trigger
COMPANY: Albaugh Inc.
FOOD USE [ ] **INTEGRATED FORMULATION [ ]**
PCC: 121011 **Decision No.** 338431

FROM: Debra Rate
Product Chemistry Team
Technical Review Branch/RD (7505C)

SRam 6/18/04
Debra N. Rate 6/18/04

TO: James Stone / Joanne Miller, RM 23
Herbicide Branch / RD(7505C)

INTRODUCTION:

The registrant has submitted the results of one year storage stability and corrosion characteristics [MRID No. 461742-01] studies for the above proposed end-use product containing Clethodim (26.4%) as its active ingredient. TRB has been asked to evaluate the product chemistry data submitted for the end-use product.

SUMMARY OF FINDINGS :

1. The end-use product contains [redacted] as the active ingredient with a product label claim of [redacted]. The nominal concentration of the AI concurs with the product label claim nominal concentration. The CSF (dated 02/16/04) is in compliance with PR Notice 91-2.

2. The storage stability (830.1617) and corrosion characteristics (830.1620) of the active ingredient, Clethodim, was evaluated for one year at 18 to 26°C. The time points for evaluation were 0, 3, 6 and 12 months. The storage container used was opaque High Density Polyethylene (HDPE). The test substance was in contact with the storage container throughout the study.

3. The chemical stability of the active ingredient was determined by the percent of the active ingredient measured in the test samples over the course of the one year study. The clethodim analysis was determined using HPLC, protocol P800. [MRID No. 461742-01]

4. The registrant visually evaluated the physical appearance of the test substance at each time point and noted any changes in color, odor, and clumping throughout the course of the study.

5. The registrant performed a physical evaluation of the product packaging after 3 months, 6 months and 12 months to determine the corrosion characteristics (830.1620) due to long term storage of the conditionally registered end-use product. The packaging was visually inspected for evidence of cracking, fogging, discoloration or distortion of the containers or their closures. The storage containers showed no signs of corrosion during the study period.

6. The analytical results of the samples under study indicate that the % of AI falls within the certified limits of the end-use product, as per the basic CSF (dated 02/16/04).

7. The data submitted corresponding to the guideline reference 830.1617 (storage and stability) and 830.1620 (corrosion characteristics) satisfy the data requirements of 40§CFR158.190. [MRID No. 461742-01]

8. All of the studies submitted [MRID No. 461742-01] have been completed in accordance with good laboratory practice (GLP). This satisfies the requirements of 40§CFR160.

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CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup B, 830.1617 (storage and stability) and 830.1620 (corrosion characteristics) are acceptable.

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830.6317(Storage Stability)

Sample Time Interval	Clethodim (%) ± SD
Initial	25.9 ± 0.21
3 months @ 18 to 26°C	26.2 ± 0.20
6 months @ 18 to 26°C	26.2 ± 0.11
9 months @ 18 to 26°C	26.4 ± 0.09
12 months @ 18 to 26°C	26.8 ± 0.16

830.6320 (Corrosion Characteristics):

1. The registrant observed no cracking, fogging, discoloration or distortion of the containers or their closures during the study intervals to the opaque HDPE packing containers.